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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,443	07/22/2003	Thomas G. Rehberger	AGP-32578-1	6437

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WHYTE HIRSCHBOECK DUDEK S.C.
555 East Wells Street
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MILWAUKEE, WI 53202-3819

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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07/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/624,443

Applicant(s)

REHBERGER ET AL.

Examiner

Irene Marx

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 19-35, 40, 41 and 43.
Claim(s) withdrawn from consideration: 1-18 and 36-39.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): _____.
13. ☒ Other: Interview Summary attached

Irene Marx
Primary Examiner
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Note:

The proposed amendment raises new issues that would require further consideration and/or search with respect to the amendment to replace “a Profile I” with “the Profile I” in claims 19 and 30, including new issues under 35 U.S.C § 112.

With regard to claims 41-44, it is noted that claim 41 was included in the new matter rejection and in the rejection under 35 U.S.C § 112, second paragraph. Clearly claim 43 was inadvertently omitted from these rejections. In addition, claims 42-44 were all inadvertently omitted from the listing of claims presented for examination. From the context of the rejections, it is clear that at least claim 43 was intended to be included in the new matter rejection, since it depends on rejected claim 40.

Response to Arguments

Applicant's arguments have been fully considered as they pertain to the claims of record but they are not deemed to be persuasive.

Applicant's argue that there is no new matter because the figures are merely different interpretations of the originally filed figures. The fact that figures are illegible upon filing is not an invitation to present a further analysis of the data not present in the original written disclosure, but rather the submission of better versions or clearer figures with the same information and configuration as originally filed. There is no clear correlation that can be readily ascertained between the new Figure I-A or Figure I-B and Figure I as filed. Applicant has not indicated the correction of an error in the original figure, but rather a further analysis of the data, which was not in possession of applicant at the time the claimed invention was made, as evidenced by the instant written disclosure. Also, the declaration clearly shows that the figure I-B pertains to an entirely new analysis of data not present in the as-filed specification. Therefore, the material added constitutes the addition of new data to the specification.

That the figures are “related” does not overcome the new matter rejection.

It is noted that the new Figures cannot be readily compared with the figure as filed, which is not clearly legible. In addition, the new Figures provide data beyond that provided in the as-filed specification. Thus, the strains encompassed by the claim designated language cannot be reliably identified. Table 6 provides strain designations and species designations, but the correlation with Profile I is unclear. Generally there is a clearer correlation between

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genus/species and DNA data. Yet the Figure and Table are not informative regarding the specific properties of the strains intended to be claimed.

Regarding “milk replacer”, this phrase appears to be intended to encompass any liquid whatsoever, even absent any nutritional content.

With respect to the prior art, the arguments presented fail to provide evidence. It is noted that the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains. That it is not explicitly disclosed does not prove that it is absent, in the absence of evidence to the contrary.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgram*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of

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establishing anticipation/non-obviousness by objective evidence shifted to Applicants.

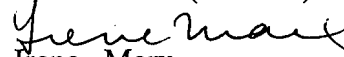
Applicants have not met that burden.

Therefore the rejections are deemed proper and are adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651